



## **A PUBLIC HEALTH APPROACH TO INTELLECTUAL PROPERTY RIGHTS**

### **Public Health Related Flexibilities in the TRIPS Agreement**

**Flexibility in the choice of patentability criteria, including for chemical entities and biologics** – World Trade Organization (WTO) members have considerable policy space to define what an ‘invention’ is and to apply rigorous standards of patentability to avoid the grant of patents that, without making a genuine technical contribution, may distort market competition. If the right standards are applied by patent offices and courts, governments may not need to resort to corrective measure, such as compulsory licenses.

**Compulsory licensing** -- Widely recognized in the legislation of developed and developing countries -and granted since the adoption of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) by the administration or courts in countries such as Thailand, Ecuador, Indonesia, India, Brazil, USA, Italy and Germany-, compulsory licenses may be necessary to correct market distortions (abuses of market power, unfair pricing, refusal to license, etc.). It is important that the procedures to grant these licenses be streamlined in order to use them effectively when needed, while ensuring that the right owner is remunerated in accordance with the economic value of the license.

**Government use authorisation** -- In many cases governments may decide –consistently with the TRIPS Agreement- to use patented inventions for non-commercial purposes, such as for ensuring the supply of essential medicines. This is an alternative to compulsory licenses that also requires the implementation of appropriate procedures.

**Flexibility in and implementation of TRIPS Agreement Article 31bis amendment to address access to medicines of countries lacking manufacturing capacity (issue of Para 6 of TRIPS and Public Health Declaration)** -- Medicines were exported under the waiver adopted by WTO in 2003 in only one case. The effective implementation and use of the mechanism now incorporated in TRIPS Article 31bis will require changes in the legislation of many potentially exporting countries (only a few have introduced such changes to date) and the adoption of adequate procedures in the potentially importing countries.

**Flexibility in test data protection** -- The TRIPS Agreement (Article 39.3) requires WTO members to protect test data against unfair competition, which does not create exclusive rights. A correct interpretation and implementation of that provision avoids the burden of creating a problematic layer of protection in addition to patent rights on pharmaceuticals.

**Avoidance of TRIPS-plus provisions and policies, including extension of patent term, data exclusivity, second use patents, border measures** -- TRIPS-plus provisions in free trade agreements (FTAs) (or resulting from accession to WTO) may negatively affect access

to medicines. Negotiators of these agreements need timely and evidence-based information to avoid, as far as possible, provisions of this kind that may reduce the accessibility and affordability of medicines through the extension (beyond 20 years) of the term of a patent, exclusive rights in respect of the results of clinical trials (data exclusivity), overbroad border measures (e.g. covering medicines in transit) and other measures affecting market dynamics.

**Mitigating implementation or effects of TRIPS-plus provisions** -- If TRIPS-plus provisions have been accepted, however, there is a range of conditions and safeguards that may be introduced to limit the possible negative impact of such provisions, such as exceptions to data exclusivity (for instance, when a compulsory license has been granted) and limitations to the scope and length of patent term extensions.

**Special TRIPS flexibilities (including exemptions) for LDCs** – Least developed countries (LDCs) need not grant patents for pharmaceuticals at least until 2033. In order to use this policy space, some LDCs would need to review their legislation or to adopt other measures to protect the government and private parties from infringement claims. They should also preserve that policy space in negotiations of free trade and other international agreements.

**Parallel importation** -- Importing medicines from countries where they can be purchased cheaper than locally, respects the intellectual property rights of right-owners while improving access to needed medicines. Appropriate measures can be adopted – consistently with TRIPS - to this end.

**Pre and post patent grant opposition, including the procedures to facilitate them** -- Procedures before many patent offices, including the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO), provide for the possibility for third parties to contribute to the examination process through ‘observations’ or ‘oppositions’ whether before or after the grant of a patent, or both. The correct implementation of these procedures helps to improve the quality of patents granted and to avoid the creation of unjustified market barriers.

**Use of competition principle and law to address misuse of patent** -- Competition law may be applied to correct market distortions created through the abuse of intellectual property rights (IPRs). There are national precedents that may provide useful examples of best practices. Guidelines for the competent authorities on intellectual property (IP) and competition law may be developed to facilitate the intervention of such authorities, when needed.

**Bolar exception** -- WTO members can use a patented medicine for the purpose of conducting research and tests for regulatory approval for generic medicines so that they can enter the market as soon as possible after the expiry of the patent. There are different modalities of ‘Bolar exceptions’ which are important to accelerate the entry of generic products and promote a dynamic market for medicines. How to best formulate a Bolar exception, consistently with the TRIPS Agreement, requires a number of technical inputs, appropriately adapted to the national context and legislation.

**Experimentation exception** -- Like the ‘Bolar exception’, the experimentation exception is permissible under TRIPS, but it may be formulated with different scope and conditions. The allowed acts would vary depending on the formulation of the exception. It will be important

to implement exceptions that as a minimum permit research on an invention for commercial and non-commercial purposes.

**Disclosure requirement, particularly for biologics** -- The full and precise disclosure of an invention is crucial for the patent system to perform its informational function. Deficient disclosure may unjustifiably extend the coverage of a patent and prevent legitimate acts by third parties. This is particularly relevant for biologicals, which cannot be described in the same way as medicines produced by chemical synthesis.

**Infringement by equivalence** -- How infringement is judged is key to provide certainty to potential market entrants regarding their 'freedom to operate'. Infringement by equivalence should be defined in a manner that does not unjustifiably extend the scope of the protection conferred by a patent.

**Provisional and permanent injunctions** -- The way in which provisional injunctions are granted may promote or distort the market dynamics. Permanent injunctions may be denied for public health reasons under certain circumstances. US jurisprudence on both types of injunctions might provide useful guidance to other countries.

**Flexibilities in enforcement of IP** -- Measures to enforce IP -such as reversal of the burden of proof, determination of damages, border measures- if overly broad, may distort competition by discouraging or preventing market entry and the availability of generic medicines. However, there is room to design such measures in a manner that is fair and equitable to all parties engaged in administrative or judicial procedures regarding IP.